Exhibit B

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MEMORANDUM

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RE: The Federal Anti-Kickback Statute and the Scope of Criminal Penalties for Violations

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I. Introduction

"Prosecutors have become the new regulators of the health-care industry. The government's anti-kickback offensive has created an approved (if narrow and awkward) set of business structures from which health-care providers deviate at their peril."[1] By "peril," these authors refer to a variety of criminal penalties that are increasingly being imposed on those who violate certain sections of the Social Security Act. This memorandum will briefly outline the nature and extent of those criminal penalties as they apply to violations of the federal anti-kickback statute and discuss the variety of business situations to which the statute applies, including the provision of discounted or free goods or services to potential referral sources, as recently addressed in yet another OIG advisory opinion posted May 9, 2008.

II. Review of Federal Anti-Kickback Statute and Criminal Penalties

By way of review, the federal anti-kickback statute criminalizes "knowingly and willfully" offering, paying, soliciting, or receiving, "any remuneration (including any kickback, bribe, or rebate) directly or indirectly" to induce the referral of any individual for any item or service which is paid for by a federal health care program, or to induce the purchase of any such item or service."[2] Those who violate this law are not only subject to mandatory exclusion from future participation in federal health care programs, but may also be liable for fines of up to $25,000, and imprisonment.[3] For the purposes of the federal anti-kickback statute, it does not matter whether any Medicare funds were actually used to pay the remuneration or whether the remuneration actually induced referrals.[4] Similarly, it does not

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1 Stanley A. Twardy & Michael P. Shea, Anti-Kickback Anxiety: How a Criminal Statute is Shaping the Health-Care Business, ABA Section of Business Law, Business Law Today, May/June 2000.

2 42 U.S.C. § 1320a-7b(b).

3 Id.; 42 C.F.R. § 1001.101.

matter whether there was any actual agreement to refer Medicare-related business in exchange for the remuneration.[5] So long as *one* purpose of the remuneration is to pay or be paid for federal health program referrals, it implicates the anti-kickback statute.[6]

III. Recent Trends in Prosecuting Health Care Fraud

The United States Department of Justice ("DOJ") has stated that "eliminating and deterring health care fraud schemes of all types are among [its] highest priorities," and that it is "committed to addressing the scope and variety of schemes in [its] efforts to successfully investigate and prosecute fraud."[7] The following statistics highlight the DOJ's level of interest in prosecuting such cases.

In 2006 alone, federal prosecutors opened 836 new criminal health care fraud investigations involving 1,448 potential defendants. Of those, 579 defendants were indicted in connection with 355 cases. A total of 547 defendants were convicted for health care fraud-related crimes.[8] Across the country, a total of 296 defendants were criminally sentenced in United States District Courts in 2006 specifically for health care fraud. Of those 296 sentenced, 167 were imprisoned. The average sentence for those defendants that were imprisoned was 41 months, or almost three and a half years.[9]

IV. Examples of Situations that May Violate the Federal Anti-Kickback Statute

Although the facts and circumstances of each case are unique, a straightforward example from August 2005, which is posted on the Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG")'s website[10] along with a list of other health care fraud-related criminal enforcement actions, involved a defendant in Florida who owned and operated several medical equipment companies and pharmacies. He was investigated and found to have made cash payments to other medical equipment companies and individuals within the industry with whom he did business. Regardless of why he may have been making such payments, this was found to be an inducement for the referral of Medicare patients amounting to illegal kickbacks that resulted in the submission of millions

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5 Hanlester Network v. Shalala, 51 F.3d 1390, 1397 (9th Cir. 1995).

6 United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

7 U.S. Department of Justice, Health Care Fraud Report for Fiscal Year 1997.

8 The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2006.

9 U.S. Department of Justice, Office of Justice Programs, Bureau of Justice Statistics, Sourcebook

of dollars worth of false Medicare claims. He was sentenced to over five years in prison and ordered to pay $3.89 million in fines.

This example involves direct cash payments, but the anti-kickback statute is actually much broader in scope. Improper "remuneration" includes not only payments in cash but payments in-kind, paid "directly or indirectly, overtly or covertly." Thus, the statute covers many other types of arrangements. Case law interpreting the anti-kickback statute indicates that remuneration can be in "forms other than cash, such as long-term credit arrangements, gifts, supplies, equipment, or the furnishing of business machines" or automobiles.[11] Examples provided by the OIG include "[a] supplier [who] gives a nursing facility non-covered medical products at no charge, provided the facility assists in the ordering of Medicare-reimbursed products."[12] The OIG has further stated that a vendor of ancillary services that provides discounts to a nursing home reimbursed through the Part A prospective payment system ("PPS") in exchange for the opportunity to provide the service to Part B beneficiaries, and bill Medicare directly for such business at its usual and customary rate (a so-called "swapping" arrangement), may also violate the anti-kickback statute.[13]

In its most recent advisory opinion on this subject (posted May 9, 2008),[14] the OIG has reinforced its longstanding position on providing free or below-cost goods or services to actual or potential referral sources that "such arrangements are suspect" under the anti-kickback statute. The opinion discusses a lab that contracts with dialysis facilities to perform Medicare-covered laboratory testing services. The Medicare reimbursement for laboratory testing services is either included in the dialysis facilities' composite rate, or paid directly by Medicare to the lab, depending on the type of test.[15] In order to retain business and compete with other labs performing the same testing services and offering similar benefits, the lab that is the subject of the advisory opinion proposed providing free test tube and specimen collection container labeling services to select dialysis facilities, which would

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11 See United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985) (quoting testimony before the Congressional Committee, H. Rep. No. 393, pt. 2, reprinted in 1977 U.S.C.C.A.N. 3039, 3048-3049); United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d, 20, 26 (1st Cir. 1989).

12 Special Fraud Alert, "Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities" (Aug. 1995).

13 Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. No. 99-2 (issued Feb. 26, 1999, posted Mar. 4, 1999).

14 Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Adv. Op. No. 08-06 (issued

ordinarily be an expense the facilities would bear.[16] Consistent with previous opinions, the OIG made clear that the situation described would likely amount to a swapping arrangement and violate the anti-kickback statute.[17]

The OIG explained that, as a starting premise, the provision of free labeling services to the dialysis facilities is a tangible, financial benefit to the facilities because they would otherwise be required to cover this expense. Further, the OIG stated that the practice of providing free labeling services essentially amounts to a discount.[18] The OIG explained that although the discount is nonmonetary, the arrangement described "poses a significant risk of improper 'swapping' of business." This is because the dialysis facilities bear some risk with respect to those laboratory tests that are covered under the Medicare composite rate (in that the rate must cover and/or exceed the dialysis facilities' costs in order generate revenue), and thus have an incentive to solicit discounts in any form. Moreover, the lab has an incentive to offer remuneration in the form of a discount in order to generate referrals by the facilities of Medicare-covered tests that are not bundled into the dialysis facilities' composite rate, but are instead separately billed to Medicare by the lab and reimbursed to the lab directly. The OIG explained, "[b]y capturing referral streams from the selected Dialysis Facilities, the Lab would likely be able to generate substantial revenue, because dialysis patients typically need lifetime laboratory testing services associated with their receipt of dialysis services."

Under these circumstances, "[b]oth parties have obvious motives for agreeing to swap nonmonetary 'discounts' on composite rate business for referrals of non-composite rate business: the selected Dialysis Facilities to maximize expense recoupment under the composite rate system and the Lab to secure lucrative business in a highly competitive market." As such, the OIG would infer that the labeling services are intended to induce the referral of additional Medicare business.[19] With respect to the fact that the labs' competitors are offering similar nonmonetary discounts to dialysis facilities with which they do business, the OIG stated, "these competitor 'discount' arrangements may similarly run afoul of the anti-kickback statute" if they are accompanied by the requisite intent to generate referrals of federal health care program business.[20] In other words, the OIG's view is that industry practice is not a justification for actions that may violate the anti-kickback statute, or a defense against governmental enforcement action.

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16 OIG Adv. Op. No. 09-06 at 3.

17 Id. at 4.

18 Id. at 5.